

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Bryan et al. PATENT NO. 5,865,846

SERIAL NO.: GROUP ART UNIT:

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FOR: HUMAN SPINAL DISC PROSTHESIS

ATTORNEY DOCKET NO.: 46739/252388

Assistant Commissioner for
Patents
Washington, D.C. 20231

DATE: February 2, 2001

PRELIMINARY AMENDMENT

Sir:

Preliminary to any examination on the merits, please amend the above-mentioned application as indicated below.

IN THE CLAIMS

Please cancel claims 5-7 without prejudice or disclaimer to the subject matter thereof.

Please amend the claims as follows.

4. (Amended) A method of surgery comprising: [the steps of removing a vertebral disc from a patient's spine, forming holes at precisely predetermined locations in the bone structure adjacent the location of the removed disc, tapping the

holes to form a female thread in each hole, and threadably implanting an anchor into each tapped hole, thereby creating reference points located precisely with respect to the patient's spine,]

(a) forming concave surfaces in the endplates of confronting vertebral bodies

[adjacent spinal bone], and

(b) inserting between the formed [bone] concave surfaces [a vertebral] an intervertebral disc endoprosthesis, [including] comprising:

(1) confronting concaval-convex supports, each support having an exterior convex surface adapted to mate with [the adjacent] one of the formed concave [spinal bone surface] surfaces, [the endoprosthesis further including] and

(2) a resilient body interposed between the concaval-convex supports[, and thereafter affixing the concaval-convex supports to the adjacent bone].

8. (Amended) A method of spinal surgery comprising: [the steps of]
forming mounting holes in one or more vertebral bodies of a patient's spine;
utilizing said mounting holes to mount a bone mill on [a] the patient's spine;
milling confronting bone surfaces on and in the patient's spine to a predetermined surface shape;
removing said mill; and [thereafter]
mounting [a vertebral] an intervertebral disc endoprosthesis having a predetermined outer surface shape [by means of the original mounting holes] so that outer surfaces of the [vertebral] intervertebral disc endoprosthesis mate [precisely] with the previously milled bone surfaces.

9. (Amended) A method of endoprosthetic discectomy surgery comprising [the steps of]

receiving information about the size, shape, and nature of a patient's involved [and proximate normal] natural spinal vertebral bodies and natural spinal vertebral discs from [known] imaging devices, [thereafter constructing at least vertebral disc endoprosthesis comprising a resilient disc body and concaval-convex elements at least partly surrounding the resilient disc body,]

removing at least the involved, damaged natural spinal [discs] disc material from the patient's spine,

forming concave surfaces in adjacent spinal [bone] vertebral bodies, and [thereafter]

implanting [the vertebral] an intervertebral disc endoprosthesis comprising a resilient disc body and concaval-convex elements at least partly surrounding the resilient disc body in the patient's spine.

Please add the following new claims.

10. The method of surgery according to claim 4, further comprising affixing the concaval-convex supports to the adjacent bone of the vertebral body.

11. The method of surgery according to claim 10, wherein the affixing comprises positive bonding between the adjacent bone and the exterior convex surface of the intervertebral disc endoprosthesis.

12. The method of surgery according to claim 4, further comprising:

(c) prior to forming the concave surfaces in the vertebral body endplates,
threadably implanting an anchor into a precisely positioned hole in the anterior
surface of each adjacent vertebral body; and

(d) affixing a bone surface milling jig to the anchors.

13. The method of surgery according to claim 12, wherein the bone surface
milling jig positions a milling head or bit, which forms the concave surfaces in the
endplates of the vertebral bodies.

14. The method of surgery according to claim 12, further comprising:

(e) removing the bone surface milling jig after forming the concave
surfaces in the endplates of the vertebral bodies.

15. The method of surgery according to claim 4, further comprising removing
damaged spinal disc material.

16. The method of surgery according to claim 4, wherein the intervertebral disc
endoprosthesis further comprises a fluid-tight seal member surrounding the resilient
body.

17. The method of surgery according to claim 16, wherein the seal member comprises a flexible polymer sheet substantially impervious to the passage of any fluid.

18. The method of surgery according to claim 16, wherein the seal member is affixed to the concaval-convex supports by a groove encircling the periphery of each support and a retaining band to retain the edge of the seal member in the groove.

19. The method of surgery according to claim 4, wherein the resilient body comprises a gasket and nucleus.

REMARKS

STATUS

Upon entry of the present amendment, claims 1-4, and 8-19 will be pending, and claims 5-7 will be canceled.

SUPPORT

Applicants have amended claims 4, 8, and 9 to correct errors and defects as indicated in the accompanying reissue declaration. Additional dependent claims 10-18 have been added to provide more complete claim coverage, and are fully supported by the specification. No new matter has been added.

Support for the changes to claim 4 can be found in the specification, *inter alia*, at column 2, lines 33-38 and at column 6, lines 43-47.

Support for the changes to claim 8 can be found in the specification, *inter alia*, at column 6, lines 43-47.

Support for the changes to claim 9 can be found in the specification, *inter alia*, at column 2, lines 52-63.

Support for claims 10 and 11 can be found in the specification, *inter alia*, at column 5, lines 7-24.

Support for claims 12-14 can be found in the specification, *inter alia*, at column 6, lines 49-67.

Support for claim 14 can be found in the specification, *inter alia*, at column 6, lines 42-43.

Support for claims 15-17 can be found in the specification, *inter alia*, at column 4, line 33 to column 5, line 18.

Support for claim 18 can be found in the specification, inter alia, at column 4,
lines 1-3.

Please charge any deficiencies or credit any overpayment in fees to Deposit
Order Account No. 11-0855.

Respectfully submitted,



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